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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/615,126 | 07/08/2003 | Yves A. Chantigny | 17166 (PC23118A) | 8071 |

7590

10/04/2005

Dr. Andrew J. Leon
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EXAMINER

GRAZIER, NYEEMAH

ART UNIT PAPER NUMBER

1626

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/615,126 | Applicant(s) CHANTIGNY ET AL. | |
| | Examiner Nyeemah Grazier | Art Unit 1626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62, 64 and 66 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 16, 17, 21, 22, 35-40, 47, 49-52, 58, 60-62, 64 and 66 is/are rejected.
- 7) ☒ Claim(s) 43 and 59 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2/22/05</u> | 6) <input type="checkbox"/> Other: _____ |

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Continuation of Disposition of Claims: Claims withdrawn from consideration are 1-7, 64, 68 (in-part), 8-15, 18-20, 23-34, 41, 42, 46, 48, 53-57, 63 and 65.

DETAILED ACTION

I. ACTION SUMMARY

Claims 1-66 are currently pending in the instant application and are subject to the required restrictions and elections as described below. Claims 63 and 65 are withdrawn under 37 CFR 1.142(b) as non-elected subject matter.

II. PRIORITY

This application claims benefit of U.S. Provisional Application, 60/394,425, filed July 8, 2002.

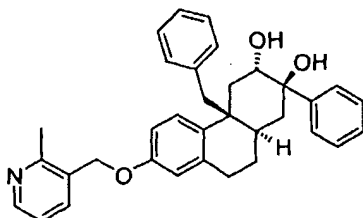
III. RESPONSE TO APPLICANT'S REMARKS

Applicant's provisional election of Group I, Claims 1-62, 64 and 66, and a provisional election of a species in the Remarks filed on August 12, 2005 is acknowledged. However, the applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, and therefore the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's elected species is Example 32 disclosed on p. 107 of the Specification. The requirement is deemed proper and is therefore made FINAL.

Example 32

(2R, 3S, 4aR, 10aR)-4a-Benzyl-7-(2-methylpyridin-3-ylmethoxy)-2-phenyl-1,2,3,4,4a,9,10,10a-octahydrophenanthrene-2,3-diol



IV. ELECTION

Status of the Claims

The elected invention for search and examination purposes are the products of Formula

(I) wherein:

X, Y, R¹, R⁴, R⁶, R⁷, R⁸, R⁹, R¹⁴, and R¹⁵ are as defined in Claim 1;

A represents the formula $-CR^6R^7-CR^8R^9-$;

R² is (C₁-C₆)alkyl, (C₂-C₆)alkenyl, (C₃-C₆)alkynyl, (C₃-C₁₀)cycloalkyl, (C₆-C₁₀)aryl, (C₆-C₁₀)aryl(C₁-C₄)alkyl or (C₃-C₁₀)cycloalkyl-(C₁-C₄)alkyl optionally substituted according to Claim 1;

R³ is (C₁-C₆)alkyl, (C₂-C₆)alkenyl, (C₂-C₆)alkynyl, (C₃-C₁₀)cycloalkyl, or (C₆-C₁₀)aryl optionally substituted according to Claim 1;

R⁵ is pyradine-(C₁-C₆)alkyl-O-, and pyradine-O-;

Scope of Withdrawn Subject Matter Not Drawn to Example 32

The remaining subject matter of claims 1-7 (in-part), 64 (in-part), 68 (in-part), 8-15, 18-20, 23-34, 41, 42, 46, 48, 53-57, 63, and 65 that are not drawn to the above invention and the subject matter described in Applicant's Response stands withdrawn under 37 CFR § 1.142(b) as being for non-elected subject matter. The compounds are not within the elected invention, which are independent and distinct from the elected invention and do not have utility with the elected compound and are therefore withdrawn by way of restriction.

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Compounds of Claim 1 and claims that depend from Claim 1 are withdrawn by way of restriction wherein

A represents the formula $-\text{CO}-\text{CR}^{10}\text{R}^{11}-$, $\text{CR}^{12}=\text{CR}^{13}$;

R^2 is (C₁-C₉)heterocyclyl, (C₁-C₉)heteroaryl, (C₁-C₉)heterocyclyl-(C₁-C₄)alkyl, (C₁-C₉)heteroaryl-(C₁-C₄)alkyl optionally substituted according to Claim 1;

R^3 is (C₁-C₉)heterocyclyl, (C₁-C₉)heteroaryl optionally substituted according to Claim 1;

R^5 as defined in Claim 1 with the exception for when R⁵ is O-alkylpyradine or O-pyradine.

The abovementioned compounds are withdrawn from consideration as being non-elected subject matter. The withdrawn compounds contain distinct substitutions such as phenols, imidazoles, triazines etc., which differ significantly in structure and function. This structural and elemental variety of substitutions is exemplified by their classifications in the U.S. classification system. For example: imidazoles are classified in 548/347.1 while triazines are classified in 544/180, etc. Therefore the compounds are withdrawn as being non-elected subject matter that differs materially in structure and composition.

V. REJECTIONS

35 USC § 102 REJECTION

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

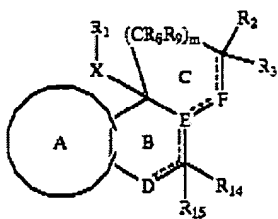
A person shall be entitled to a patent unless –

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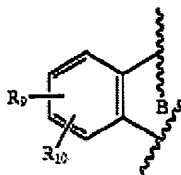
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 16, 17, 21, 22, 35-40, 44, 45, 47, 49-52, 58, 60-62, 64 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen, et al. (EP 1087709 A2).

Chen et al. discloses compounds of the following generic formulas:



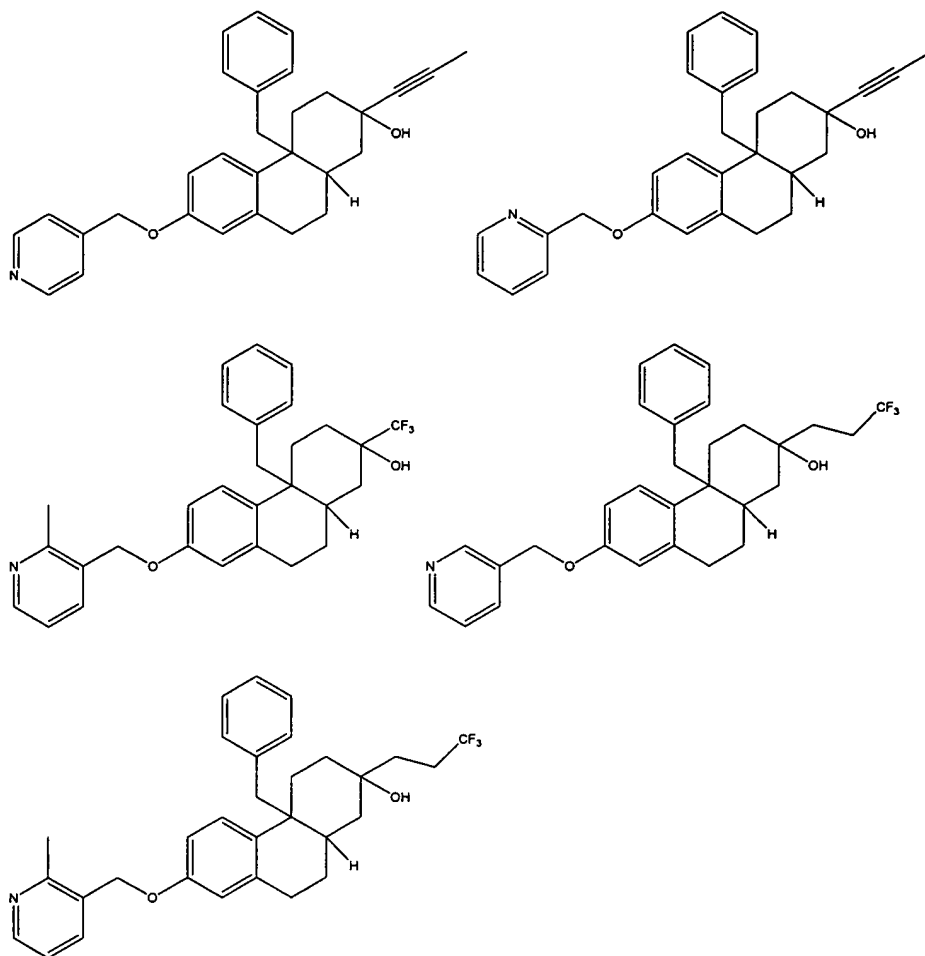
Wherein A is



D is CR_7R_{16} , **E** is CR_6 , **F** is CR_4R_5 , **X** is CH_2 , **R**₁ is (C₁-C₆)alkyl, **Z**-aryl (aryl is phenyl and **Z** is C₀alkyl); **R**₈, **R**₉, **R**₁₄, **R**₁₅ are independently H, halo, (C₁-C₆)alkyl, substituted with 0-3 halo, (C₂-C₆)alkenyl, substituted with 0-3 halo, (C₂-C₆)alkynyl substituted with 0-3 halo, OH; **R**₂ is H, halo, -OH, (C₁-C₆)alkyl substituted with 0-1 -OH, $\text{NR}_{12}\text{R}_{13}$ (**R**₁₂ and **R**₁₃ are H or (C₁-C₆)alkyl); **R**₃ is H, (C₁-C₁₀)alkyl, (C₂-C₁₀)alkenyl, (C₂-C₁₀)alkynyl, -Z-aryl, for example. (*See generally*, Chen et al., ¶ 0040).

Chen et al also discloses the following compounds exemplified as species.

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(See CAPLUS registry numbers: 305822-13-3, 305822-14-4, 305822-22-4, 305822-23-5, and 305822-25-7 attached hereto). (See also Chen, et al. EP 1097709 A2, ll. 0040-0043).

Chen, et al. anticipates the instant invention of the compounds of Formula (I) wherein X and Y are hydrogen and either X or Y is a halogen, or (C1-C6) alkyl (Chen, et al., ¶ 0040, p. 2, l. 56), and R⁵ is -O-CH₂-pyridine optionally substituted with CH₃; A is CR⁶R⁷-CR⁸R⁹ and R⁶ - R⁹ are hydrogen; R¹ is -CH₂-Phenyl; R² is CCCH₃, (CH₂)₂CF₃; and R³ and R⁴ are each hydrogen.

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Claims 1-7, 35, 37, 47, 49-52, 58, 60, 62, 64 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Dow, et al. (WO 2000066522 A1).

Dow, et al. anticipates the instant invention of the compounds of Formula (I) wherein **X** and **Y** are hydrogen and **R**⁵ is –O-CH₂-pyradine or –O-CH(CH₃)-pyradine optionally substituted with CH₃, halogen or methoxy; **A** is CR⁶R⁷-CR⁸R⁹ and **R**⁶ – **R**⁹ are hydrogen; **R**¹ is –CH₂-Phenyl, or C₃ alkyl, C₅ alkyl; **R**² is CCCH₃, n-propyl, (CH₂)₂CF₃, CF₃, chloroethynyl, 3-methyl-1-butyryl, 2-methylpropyl, 3-methylbutyl, 3-methyl 3-hydroxybutyl, 4-methyl pentyl, 3,3-dimethylbutyne, propanol, cyclopropylethyl, 3,3-dimethylbutyl, pentynyl, butynyl, methyl; and **R**³ and **R**⁴ are each hydrogen. (See CAPLUS Registry numbers: 305822-12-2, 305822-13-3, 305822-14-4, 305822-15-5, 305822-16-6, 305822-17-7, 305822-18-8, 305822-19-9, 305822-21-3, 305822-22-4, 305822-23-5, 305822-24-6, 305822-25-7; 305825-66-5, 305826-00-0, 305826-06-6, 305826-07-7, 305826-11-3, 305826-12-4, 305826-20-4, 305826-21-5, 305826-25-9, 305828-31-3, 305828-32-4, 305828-52-8, 305828-53-9, 305828-66-4, 305828-69-7, 305828-78-8, 305828-79-9, 305828-82-4, 305828-83-5, 305829-02-1, 305829-03-2, 305829-06-5, 305829-09-8, 305829-24-7, 305829-25-8, 305829-31-6, 305829-47-4, 305830-37-9, 305830-47-1, and 305830-54-0 attached hereto).

VI. OBJECTIONS

Claim Objections

Claims 17, 21, 22, 35-40, 43-45, 47, 49-52, 58-61 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other

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multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.


CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781. The examiner can normally be reached on Monday through Friday from 8:30 a.m. - 5:00 p.m..

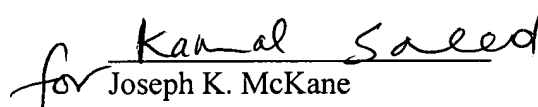
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Very truly yours,


Nyeemah Grazier, Esq.

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